

Board of Scientific Counselors

Office of Research and Development
United States Environmental Protection Agency

Second Program Review of the National Center for Environmental Assessment (NCEA)













Final Report of the Subcommittee on the Review of NCEA

January 6, 2003



NOTICE

This report has been written as part of the activities of the Board of Scientific Counselors (BOSC), a public advisory group that provides objective and independent counsel to the Assistant Administrator for the Office of Research and Development (ORD) of the U.S. Environmental Protection Agency (EPA). The Board is structured to provide a balanced expert assessment of the management and operation of ORD's research programs and its utilization of peer review. This report has not been reviewed for approval by the Agency; and hence, the contents of this report do not necessarily represent the views and policies of the EPA or other agencies in the federal government. Mention of trade names or commercial products does not constitute a recommendation for use.

TABLE OF CONTENTS

Pre	face		ounselors Executive Committee	
	Ros	ter of the Board of Scientific Counselors Executive Committee	5	
	Ros	ter of the Board of Scientific Counselors NCEA Subcommittee	7	
	List	of Acronyms	8	
1.0	Exe	cutive Summary	9	
2.0	Laboratory Review		11	
	2.1	Planning and Integration	11	
	2.2	Research Strengths and Challenges	19	
	2.3	Performance	22	
	2.4	Measures of Success and Future Needs	25	
3.0	Rec	ommendations	29	
App	endi	ces		
	A.	List of Documents Made Available to the Subcommittee	33	
	В.	Summary of NCEA Actions With Respect to the Recommendations of the		
		1998 BOSC Review	35	
	C.	NCEA Self-Study	37	

PREFACE

The Board of Scientific Counselors (BOSC) provides objective and independent counsel to the Assistant Administrator of the Office of Research and Development (AA/ORD) on the management and operation of ORD's research programs. The primary functions of BOSC are to: (1) evaluate science and engineering research programs, laboratories, and research-management practices of ORD and recommend actions to improve their quality and/or strengthen their relevance to the mission of the EPA; and (2) evaluate and provide advice concerning the use of peer review within ORD to sustain and enhance the quality of science in EPA.

In spring 2000, at the request of Henry Longest II, AA/ORD, the BOSC undertook peer reviews of the ORD Laboratories and Centers. This request came approximately 4 years after the initial BOSC review of the Laboratories and Centers, which was completed on April 30, 1998. Accordingly, the BOSC began the task of conducting programmatic, as opposed to scientific or technology, reviews of the Laboratories and Centers and proceeded to establish policies and procedures for conducting such reviews. The scheduled reviews occurred as follows:

- ♦ National Risk Management Research Laboratory, August 21-22, 2001, at Cincinnati, OH
- ♦ National Center for Environmental Assessment, October 10-11, 2001, at Washington, DC
- ♦ National Health and Environmental Effects Research Laboratory, October 30-31, 2001, at Research Triangle Park, NC
- ♦ National Exposure Research Laboratory, December 18-20, 2001, at Research Triangle Park, NC
- ♦ National Center for Environmental Research, January 23-24, 2002, at Washington, DC

As constructed, the Laboratory and Center reviews are expected to lead to a better understanding of the strategies employed by the respective Directors in accomplishing their missions, and to a better understanding as to how these strategies are implemented. BOSC also expects to develop a clearer perspective on how the operation of the Laboratories and Centers articulates with the strategic plan of the ORD and relates to the Multi-Year Research Plans (MYPs).

Each Laboratory and Center review consisted of two parts. The first part was a written self-study submitted to the review committee in advance of the date of its review, and the second part was a 2-day site visit conducted by the review committee. In the self-study, Directors were asked to prepare responses to questions aimed at a programmatic assessment of the organization. During the first day of the site visit, the Director made a brief presentation about the organization and was then asked to respond to questions from the review committee about the self-study document. Later, case studies were presented that reflected how the organization successfully addressed a specific issue faced by the Agency. The first day concluded with a poster session or informed interviews attended by staff scientists and other professionals. On the second day, the committee drafted a report that contained its findings and recommendations. At the end of the day, an exit interview was conducted with the Director.

All review teams were organized as Subcommittees of the BOSC and were headed by a chair and vice chair, both members of BOSC. Additional members of the Subcommittee were selected on the

basis of an appropriate technical discipline as well as having broad experience in science and research management, planning, and communication. The Chair of the BOSC attended some reviews as an ex-officio member.

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LIST OF ACRONYMS

AAAS American Association for the Advancement of Science

AA/ORD Assistant Administrator for the Office of Research and Development

ACD Assistant Center Director

AD Associate Director

APG Annual Performance Goal APM Annual Performance Measure

ATSDR Agency for Toxic Substances and Disease Registry

AWWARF American Water Works Association Research Foundation

BOSC Board of Scientific Counselors

CRADA Cooperative Research and Development Agreement

EGG Executive Guidance Group

EPA Environmental Protection Agency FDA Food and Drug Administration

GCC Global Climate Change

GIS Geographical Information System

GPRA Government Performance and Results Act
IARC International Agency for Research on Cancer
IEUBK Integrated Exposure Uptake Biokinetic
IPCS International Program for Chemical Safety

IRIS Integrated Risk Information System

IT Information Technology

MOU Memorandum of Understanding

MYP Multi-Year Plan

NCEA National Center for Exposure Assessment NCTR National Center for Toxicology Research

NICHD National Institute of Child Health and Human Development

NIH National Institutes of Health

NIOSH National Institute for Occupational Safety and Health

NSF National Science Foundation NTP National Toxicology Program

OECD Organization for Economic Cooperation and Development

ORD Office of Research and Development

OSHA Occupational Safety and Health Administration
OPPTS Office of Prevention, Pesticides and Toxic Substances

OSP Office of Science Policy

OSWER Office of Solid Waste and Emergency Response

PBMK Physiologically-Based Pharmacokinetics

RCT Research Coordination Team
RFA Request for Application
RfC Reference Concentration
RTP Research Triangle Park

SETAC Society of Environmental Toxicology and Chemistry

SRA Society for Risk Analysis
STAR Science to Achieve Results

TERA Toxicology Excellence for Risk Assessment

WHO World Health Organization

WTC World Trade Center

1.0 EXECUTIVE SUMMARY

The Board of Scientific Counselors (BOSC) established the Subcommittee for the National Center for Environmental Assessment (NCEA) to act as a resource for NCEA. This review is the second undertaken by the BOSC.

NCEA's key accomplishments as identified by the Subcommittee since the last review included: the completion of the Center's Strategic Plan in 2000, a targeting of the risk assessments it performs to cutting-edge assessments rather than routine ones, improvements in the proportionate representation of ecological assessments to health assessments, the creation of an extensive Web site to enhance communication, and capabilities to provide environmental assessment resources in response to the September 11th attack.

Areas in which the Subcommittee can work with NCEA in the future include benchmarking, identification and evaluation of its client base, the development of a strategy for replacing staff members as they retire, the enhancement of programs for mentoring staff and leadership development, and regular tracking and evaluating of the Center's accomplishments.

2.0 LABORATORY REVIEW

The Board of Scientific Counselors (BOSC) established the Subcommittee for the National Center for Environmental Assessment (NCEA) of the Office of Research and Development (ORD) at its meetings during 2000 and 2001. This subcommittee was one of five Laboratory/Center Standing Subcommittees established by the BOSC to act as a resource for the ORD Laboratories and Centers.

The NCEA Subcommittees' work began with a series of study questions and site visits to update previous reviews and target new issues. The final report of the first BOSC review of NCEA was issued on April 30, 1998. NCEA forwarded its response to the first review to the Assistant Administrator of ORD (AA/ORD) in January 1999. NCEA also was the focus of the Review by the Assessment Subcommittee for the Management Review of the Particulate Matter Research Program, which was completed in December 2000.

The Subcommittee members were Dr. Rae Zimmerman (Chair), Dr. Daniel Acosta, Jr. (Vice Chair), Dr. Anne Fairbrother, and Dr. Michael R. Greenberg. On October 10-11, 2001, the Subcommittee members (with the exception of Dr. Greenberg who was ill) met with the NCEA Director and various staff at NCEA's headquarters in Washington, DC. This meeting was open to the public. Details of the process of the meeting are summarized in "Summary Minutes of Public Meeting, October 10-11, 2001." A list of the materials distributed at the site visit is included in Appendix A.

The review of NCEA followed a set of questions developed by the entire BOSC for all of the Standing Subcommittees, which provides the organization for this report.

2.1 Planning and Integration

2.1.1 How does NCEA's strategic plan articulate with the ORD Strategic Plan and the EPA Strategic Plan?

The planning process within the U.S. Environmental Protection Agency (EPA) flows from the EPA Strategic Plan, through ORD's Strategic Plan, to NCEA's Strategic Plan. These plans were produced pursuant to the Government Performance and Results Act (GPRA). NCEA's current strategic plan (dated January 31, 2000) was prepared prior to formal issuance of the latest draft of ORD's Strategic Plan (dated January 2001). In spite of the fact that the two plans do not coincide in time, NCEA is to be commended on how well the two plans map together.

<u>Recommendation 1</u>: NCEA should await the next ORD Strategic Plan revision before updating its own strategic plan to bring the goals of the two plans into greater alignment.

2.1.2 What are NCEA's priorities and directions for the next 5 years? Include NCEA's research portfolio and multi-year planning efforts.

NCEA's priorities and directions over the next five years are reflected in the ORD-wide Multi-Year Plans (MYPs). ORD intends to use the MYPs as frameworks in making annual budget decisions. The ORD planning process retains sufficient flexibility to incorporate new ideas or to make necessary redirections, so that, for example, it could retain its responsiveness to unanticipated events such as the September 11th attack.

Multi-Year Plans

ORD has initiated several (N=16) long-term (e.g., 5+ years) MYPs that contain its research strategies. These are integrated across the Laboratories and Centers, and NCEA staff has played a key role in planning and writing several of the MYPs. According to material distributed at the October meeting in Washington, DC, NCEA has a formal role in 14 of the 16 EPA/ORD MYPs that currently are in preparation or in various stages of review. NCEA staff members are lead authors for three of the plans—Air Toxics, Global Change, and Mercury, and co-lead authors with members of other Laboratories or Centers for two plans—Ecosystem-Ecological Assessment and Human Health-Human Susceptibility. Each MYP receives direction from an Executive Guidance Group (EGG). The NCEA Director is a member of the EGG for three other MYPs—Tropospheric Ozone, Hazardous Waste, and Socioeconomics—and the NCEA Associate Directors for Health and for Ecology are on the EGGs for six others—Drinking Water, Safe Food, Contaminated Sites, Ecosystem Protection, Endocrine Disruptors, and Pollution Prevention. These activities reflect NCEA's support for and participation in the ORD process of multi-year planning, as well as interaction with other Laboratories and Centers in the development of these plans.

Once these plans are implemented, they should further help the integration of ORD-supported research across the risk assessment/risk management paradigm (exposure – effects – characterization – risk management). NCEA should continue to suggest research needed for risk characterizations and assessments so that the ORD Laboratories/Centers and the ORD Science to Achieve Results (STAR) grants program can initiate appropriate research activities in these areas. In this way, NCEA can provide a comprehensive oversight role for the incorporation of risk assessment and risk management across ORD. For example, NCEA publishes "research needs" documents associated with the Air Quality Criteria Documents developed on a 5-year cycle. In general, these documents lay out suggested areas where further research is needed. NCEA should continue this practice in all of its assessments and assure that such research needs are brought forward for consideration in ORD's annual planning and budgeting process.

<u>Recommendation 2</u>: NCEA should continue to identify the research needed to reduce uncertainties in risk assessment and to provide these research needs as input to ORD's annual budgeting process.

Planning for Unanticipated Events or Needs

The September 11, 2001 attacks and the anthrax cases that followed raise, the issue of how long-term planning within an essentially research-oriented agency can rapidly respond to emergencies and incorporate planning for unanticipated events into its long-term planning processes. Goal #4 in the ORD Strategic Plan, "to integrate environmental science and technology to solve environmental problems" allows ORD, as well as NCEA staff, to regard unanticipated events that result in or originate from environmental problems as a high priority.

NCEA has experts who can be called on when unanticipated events occur. NCEA's resources for emergencies include its expertise, information, and reputation as a repository of data. NCEA's past role in emergencies has included responding to the task force on the impact of oil fires in Kuwait, Indonesia, and Southeast Asia. In the World Trade Center (WTC) disaster, NCEA's initial role was to evaluate the monitoring needs and ways in which ORD could augment regional and state office monitoring capabilities, including sample analysis, to help evaluate and assess health impacts. NCEA staff has the lead to complete a health risk assessment of the contaminants released in the

WTC collapse. NCEA engages in the distribution of fact sheets on emergencies as part of its Web presentation. It also has been drawn into the evaluation of the potential for future threats. NCEA considers itself to be flexible enough to adapt to such needs.

Because EPA is a regulatory agency that must respond to both scheduled and unforeseen events, scientists within ORD frequently are called upon to provide review and other expert advice to the Program Offices. While Program Office needs often can be anticipated and built into the budget planning cycle, many (particularly emergency events) cannot be foreseen 2 years in advance. For example, ORD has identified 86 regulatory activities that potentially will require scientific review during the next 6 months. Most of these have not been anticipated or accounted for in the budget planning over the past 2 years. Therefore, NCEA and the ORD Laboratories must be given the flexibility to respond to short-term, immediate needs. Anticipating that need for flexibility will continue to occur. ORD is encouraged to build flexibility into its budget process, and to continue to use mid-year adjustments to allow the Laboratories and Centers to report delays in planned deliverables due to unanticipated events. Staff needs to be aware that management acknowledges such adjustments in priorities and that such changes will not detract from achieving high performance ratings or promotion requirements.

<u>Recommendation 3</u>: NCEA's response to unanticipated events is notable and critical, and in some way these needs should be integrated into the NCEA, ORD, and EPA strategic planning processes, recognizing that these particular needs are episodic, unexpected, with often uncertain and unpredictable resource needs. NCEA should assess whether, in fact, mechanisms do exist for effective emergency response and ensure that emergency provisions are a part of its plan.

2.1.3 How does NCEA integrate research with the other ORD Laboratories and Centers according to the risk paradigm?

NCEA's Role in the Risk Paradigm

NCEA plays a pivotal role in meeting the Agency's need for the use of sound science in risk management decisions. NCEA fills the risk characterization function within the ORD risk assessment paradigm. By its very nature, risk characterization requires effective communication between risk assessors and those who will be using the information for management decisions, as well as successful communication with scientists that generate the information used in the assessment. The challenge for all risk assessors is to provide the information needed for risk management, integrating the concerns of risk management, without stepping into the manager's decision role and without stepping outside the risk assessment process for the pursuit and development of new knowledge. Generation of data to be used in the risk assessment should be the purview of the ORD Laboratories, although NCEA may direct attention to data gaps and the type of research that is needed to fill those gaps.

It is tempting for NCEA to be the risk assessment "do-ers" rather than the risk assessment developers. NCEA recognized this temptation since the last BOSC Subcommittee review and has revised its slogan accordingly. NCEA now undertakes cutting edge risk assessments and provides overall guidance, methods, and tools for Program and Regional Offices, rather than undertaking routine or nonprecedent-setting risk assessments.

Developing this guidance requires that it be tested to make sure recommended processes work, particularly because NCEA guidance is developed for new and emerging areas without a large case history upon which to build. Furthermore, the credibility of NCEA scientists and their recommended guidance and process developments is enhanced if they have firsthand experience with all the difficulties and controversy embodied in the risk assessment process.

The BOSC encourages NCEA to be more proactive in identifying potential clients for its work products. It would help focus, target, and organize its programs. NCEA currently has a historic client base, most notably EPA's Office of Air and Office of Water, with the Office of Solid Waste and Emergency Response (OSWER) represented as well. NCEA reports that it receives relatively little funding for projects in support of the Office of Prevention, Pesticides, and Toxic Substances (OPPTS). Were these resources available, NCEA could expand the extent to which it both learns from and educates OPPTS in various aspects of the risk assessment process. Similarly, NCEA could target Regional Offices more fully as clients for its work. By regarding the entire Agency as possible clients, NCEA has the potential to be more successful in acquiring resources, e.g., to expand its ecological risk assessment budget (see further discussion below), and to standardize risk assessment practices across the Agency.

Laboratory and Center Integration

NCEA has a number of mechanisms for working together with other Laboratories and Centers within ORD, which provide the potential for integrating the risk paradigm, as follows:

- ☆ Multi-Year Planning. As described above, NCEA staff members are involved with other Laboratories and Centers in a number of the MYPs, as lead authors or co-authors and on the EGG and ORD Science Council.
- ♦ ORD's Extramural Grant Program. NCEA participates in NCER's administration of the ORD extramural grants program by recommending research topics, assisting with drafting Requests for Applications (RFAs), reviewing and commenting on RFAs, and reviewing proposals for relevance to the EPA and ORD missions and to the RFAs.
- Assistant Center Directors (ACDs). As with other ORD Laboratories and Centers, NCEA has ACDs that interface with other Divisions within ORD as well as with Program Offices.
- ♦ <u>Scientist Collaborations</u>. There are a large number of collaborative activities involving scientists from the different ORD Laboratories and Centers.

NCEA (and other ORD Laboratories and Centers) would benefit from development of a computerized tracking system that can integrate timelines and deliverables within each of the Research Strategies. This would, by necessity, result in integration across all ORD sectors, recognizing explicitly the interaction (or lack thereof) among them. It also would allow for real-time planning, such that if one deliverable is delayed, those that are connected are quickly identified and potential additional delays can be anticipated. Commercial software, such as Microsoft Planner®, is available for this type of project management, although the Agency may have similar in-house software available. The Subcommittee recognizes that this may be a role of ORD's Office of Science Policy (OSP); however, NCEA management must have a way to view the plans and to input information related to the Center's project implementation plans and deliverables.

<u>Recommendation 4:</u> The BOSC endorses NCEA's move away from conducting a large number of routine risk assessments and urges NCEA to continue to focus on precedent-setting or national-scale assessments. The process by which NCEA decides on which risk assessments to undertake should be articulated.

<u>Recommendation 5</u>: With respect to its work in general, the BOSC suggests that NCEA look across the Integrated Research Strategies or Multi-Year Plans, and identify its areas of interest and focus over the next 5 to 10 years.

<u>Recommendation 6</u>: The BOSC recommends that NCEA combine risk management and risk assessment in its work; that is, coordinate analytic and deliberative processes as recommended in the National Research Council's report *Understanding Risk* (1996). Also, NCEA should proactively incorporate life cycle assessment in its work. Additional resources may be needed to undertake this task.

<u>Recommendation 7</u>: The BOSC encourages NCEA to be more proactive in identifying potential clients for its work products as a basis for focusing and targeting its programs. This should be an integral part of developing communication strategies for research results.

2.1.4 How does NCEA integrate research across and within its Divisions according to the risk paradigm?

NCEA's Divisions are geographically based. Its three divisions are located in Washington, DC; Research Triangle Park (RTP), NC; and Cincinnati, OH. NCEA reports some cross-division discussions and projects, and this should be expanded, taking into account the tradeoff between the economies associated with coordination versus geographic specialization. Development of cross-division project teams will facilitate such an effort. NCEA-Cincinnati's model of teams with rotating leadership (dependent upon the particular focus of each project) is an excellent step towards integration of multiple disciplines (especially human health and ecological assessments), and could be used as a model for cross-division coordination.

Each division specializes in a particular aspect of risk assessment, although the larger divisions contain more than one specialty. The Washington, DC Division houses programs in both ecological risk characterization and human health assessments (particularly exposure factor delineation). In addition, the Washington, DC Division provides some support for air quality, water quality, and ecology, and most of the support for pesticides, toxics, and the Superfund program. The RTP Division primarily specializes in air quality for both mobile and stationary sources in support of the Office of Air. The Immediate Office (co-located with the Washington, DC Division) includes the Global Climate Change program. The Cincinnati Division specializes in water quality with some ecological risk assessment work (shared with the Washington, DC Division). The Cincinnati Division also is the most proactive in incorporating new social science concepts into ecological risk assessment processes. Because the RTP and Cincinnati Divisions are separated geographically and have distinctly different missions, it will be most difficult for these two groups to find common grounds for collaboration.

Recommendation 8: NCEA should continue to enhance communication among Division Directors to foster interdisciplinary work across the divisions. The Center should consider methods for integrating staff, including details and rotations among divisions, occasional

interdisciplinary science retreats on topics requiring input from across divisions, and other performance incentives to establish collaborative projects.

<u>Recommendation 9</u>: In order for NCEA to coordinate the risk assessment functions among the various divisions, its current functions in this area should be clearly articulated.

2.1.5 How does NCEA integrate research with EPA's Program and Regional Offices, other federal agencies, and other research centers worldwide?

Within EPA

NCEA staff members are active participants in projects coordinated through the Risk Assessment Forum, which develops science policies and guidelines for application throughout the Agency. As noted above, the multi-year planning efforts have created opportunities for integrating research across EPA, as well as across the Laboratories and Centers. The process of accomplishing this should be described.

NCEA reports that intra-Agency discussions and coordination occur at the ACD and Associate Director (AD) levels, both informally through the weekly meetings of the Research Coordination Teams (RCTs), and through the more formal process of the ORD Science Council.

NCEA has reported various joint activities with EPA Program Offices, such as management and development of research partnerships through the Office of Water with outside organizations, such as the American Water Works Association Research Foundation (AWWARF) and the Microbial and Disinfection By-Products Research Council (NCEA Self-Study in Appendix C, Chapter 1, p. 23).

Other Federal Agencies

According to NCEA, the Center is represented on the working groups of a number of research efforts in other federal agencies. A key area of coordination with other federal agencies occurs in children's health research. As is indicated by NCEA in its self-study report and in more detailed information, two NCEA professionals serve on the multi-agency Coordinating Committee of the National Institute of Child Health and Human Development (NICHD), one of the National Institutes of Health (NIH).

Other Research Centers

NCEA reports using public-private partnerships for research. In its Global Climate Change (GCC) program, public-private partnerships were reported with Johns Hopkins' School of Public Health for a discipline-specific sector (health) and with Pennsylvania State University, University of Michigan, and Southern University for regional assessments. Memoranda of Understanding (MOU) are a vehicle used by NCEA to establish partnerships. The Center has MOUs with the University of Virginia's Center for Risk Management of Engineering Systems and the State of California EPA's Office of Environmental Health Hazard Assessment (NCEA Self-Study, Chapter 1, p. 23).

NCEA has identified some international organizations that have been clients of its projects, such as the World Health Organization (WHO) International Program for Chemical Safety (IPCS).

Recommendation 10: NCEA should explore measures of the extent, diversity, and nature of its intra-ORD and intra-EPA activity and keep track of them as well as track communications on a regular basis, perhaps incorporating them into the GPRA framework. These measures should include the nature of those interactions and the outcomes. This should occur on a regular basis to ensure that intra-EPA integration of research is occurring and to understand how it is occurring.

2.1.6 Specifically, how has NCEA incorporated social and behavioral science into its research program?

In its self-study, NCEA identified a number of program areas, particularly in health risk assessments, that deal with the social dimensions of risk. These appear in the form of identifying vulnerable populations and population-specific risk factors, developing population-specific exposure factors in its *Exposure Factors Handbook*, and highlighting risk perception as a component of risk assessment and management.

Human health assessments would benefit from guidance on how to come to agreement on the exposure pathways and type of communities that would be exposed to the hazards of potential concern. This will require expertise in the social and behavioral sciences. The effort to delineate different exposures in the Exposure Factors Handbook is a step in this direction, but should not be viewed as complete or sufficient.

Moreover, one of the GPRA goals, "Safe Communities" (Goal 4) in which social and behavioral science would play a large role, has not been funded sufficiently for NCEA to address it as much as it has addressed other programs.

Few staff positions within NCEA are filled from social science areas; however, it is notable that the background of the Acting Director of NCEA is public administration and a new Deputy also is from a social science discipline.

<u>Recommendation 11</u>: To better accomplish those goals requiring social science expertise, as well as to further the development of guidance in risk communication, NCEA is encouraged to consider hiring social scientists, either as AAAS Fellows, post-doctorals, or permanent staff drawn from the fellow and post-doctoral groups.

2.1.7 How has NCEA achieved/maintained a balance between human health research and ecological research?

NCEA has been assessing the integration of human health risk assessments and ecological risk assessments. Scientists and staff have begun talking about this issue, and a few initiatives are underway. To date, NCEA has developed several case studies of how to incorporate economic considerations into ecosystem valuation. This fits into the broader activity being undertaken, of providing guidance for setting Assessment Endpoints in ecological assessments. NCEA is encouraged to continue these activities, but to broaden them to the human health arena as well.

NCEA is justifiably proud of having increased the Ecological Risk Assessment budget, such that it now comprises approximately 15 percent of NCEA's total budget. The NCEA staff seems enthusiastic about the possibilities of integrating the two areas, and observed that the integration is

enhanced through the field of ecotoxicology, where a natural combination of ecology and human health occurs.

NCEA identified some specific areas as being fruitful for integration, and in some areas such integration already has occurred:

- ❖ The Global Climate Change Program provides a good example of such an integrated approach, with its assessment of how changing climate will alter the distribution of disease vectors and pesticide use, with subsequent potential ecological effects.
- \$\text{Studies of and experiences in the Arctic, where humans are very involved with the environment, could be transferable to other areas.
- ♦ West Nile Virus demonstrates an ecological (crows and possibly squirrels) and health link that may be driven by global climate change.
- Hantavirus Pulmonary Syndrome in the Southwest, where weather, climate, mouse populations, and exposures are linked—NCEA staff pointed out that this integrative work had led to the development of risk maps by a researcher at Johns Hopkins University.
- Invasive species may be both a health risk and an ecological risk (e.g., foreign species of mosquitoes that are more efficient vectors of zoonotic disease).

Conceptual obstacles that NCEA identified to encourage health scientists and ecologists working together included the fact that improvements in human health can be stressors on the environment, thus creating an ostensible conflict. For example, if people live longer and use more resources, they put more stress on ecosystems. However, sometimes health and ecological endpoints go in the same direction and reinforce rather than conflict with each other.

At the management level, examples exist where the teams are integrated. NCEA used its retreat in May 2001, to address the integration issue. The ecology group has been more inclined toward integration than the health assessment group. The traditionally trained field ecologists are more compatible with health epidemiologists—the population and outcome structure is similar as are ways of predicting futures. Staffs are quickly becoming interdisciplinary teams to address some emerging problems. The Cincinnati Division was cited as the best example of integration. The Air Quality Criteria Documents also were cited as examples of where health and ecology sections are written together.

<u>Recommendation 12</u>: The BOSC endorses NCEA's practice of establishing interdisciplinary teams, with human health risk assessors and ecological risk assessors working together on the same assessments (Global Climate Change and "place-based" assessments rather than single chemical assessments, are examples).

Recommendation 13: The BOSC encourages NCEA to continue to increase its interest and investment in ecological risk assessment. While other portions of the government also conduct research in human health risk assessment and toxicology, the EPA is the principal agency conducting ecological assessments and developing guidance for such work.

<u>Recommendation 14</u>: NCEA has made progress in integrating ecology and human health assessments, and it is encouraged to continue to advance the state-of-the-science and practical applications in integrated assessment.

2.1.8 Specifically, how has NCEA's research management and research program changed since the last BOSC review?

The report of the last BOSC review of NCEA was issued on April 30, 1998. NCEA forwarded its response to the first review, including ways in which it was planning to respond to the recommendations, to the AA/ORD in January 1999. Some of these responses are updated in the NCEA Self-Study, Chapter 1, p. 31, and Chapter 2, pp. 8-10. In the self-study report and during the October 2001 meeting, NCEA focused on one particular recommendation—the issue of focus, which the Center has had difficulty implementing. To respond to this issue, NCEA has decided to focus its risk assessment work on those that are "precedent-setting or of national significance."

The responses to each of the recommendations in the 1998 report are summarized in Appendix B.

2.2 Research Strengths and Challenges

2.2.1 What are NCEA's unique research capabilities and strengths to accomplish its objectives?

NCEA has set ambitious targets for itself. During a period when many federal government departments and agencies have stepped back from their global missions because of a lack of resources, NCEA appears not to have done so. The Center has plans to work on the most complex and important risk assessments. In its response to the self-study questions, NCEA lists the following as illustrations of the Center's work in developing practical tools for risk assessors in the EPA Program and Regional Offices and state and local governments:

- ♦ Benchmark dose modeling guidance and software
- ♦ Stressor identification guidance
- Physiologically-based pharmacokinetics (PBMK) modeling
- ♦ All-ages lead modeling
- ♦ Multi-pathway exposure modeling.

NCEA's most important and academically challenging risk assessments currently in progress or recently completed include health risk assessments of ammonium perchlorate, benzene, butadiene, diesel, dioxin, trichloroethylene, and tetrachloroethylene. Similarly challenging ecological and integrated assessments are underway on targeted geographic areas such as the Arctic and on aspects of global climate change.

NCEA also stakes out synthesis and integration across risk assessment, and some examples are found on the Center's Web site (http://www.epa.gov/ncea) of the products of such synthesis. Staff members point to efforts to integrate the work of EPA policy analysis and economics groups, other federal agencies, and the WHO, as mentioned in Section 2.1.5.

<u>Recommendation 15</u>: To evaluate and communicate how NCEA accomplishes its risk assessments, the Center needs to describe its process of synthesis and integration across the stages of risk assessment and how it engages the different entities within ORD, EPA, and the research community in producing such integration.

2.2.2 How does NCEA communicate its results within the organization, within ORD, within EPA, to outside agencies, and to the outside world?

NCEA understands the need to communicate its work. Yet, such an undertaking is extremely resource intensive. To date, the major mechanism for communication is the Intranet/Internet. Members of the review team have used this site and reviewed it again. The site contains some extremely well done studies.

Information Technology (IT) Resources, Usage, and Staffing

IT is a valuable resource ORD-wide and Agency-wide, as well as for outside organizations. NCEA has produced an upgraded, new Web site (http://www.epa.gov/ncea) that has significantly promoted outreach and education. NCEA reports that the Web site is heavily accessed, with approximately 510,000 hits per month. The Center reports having a regular base of about 16,000 unique customers each month who may use the site one or more times a month. On average NCEA's customers are viewing or downloading about 30 gigabytes of data each month. Only about 10-15 percent of the Center's customers are from the federal government (including EPA), and more than one-third of NCEA's customers are from foreign countries. Evaluating the use of its Web site, as well as specific resources such as IRIS, are important IT-related responsibilities for NCEA.

NCEA has a core IT staff in-house, with particular emphasis in Web applications. At this time, NCEA outsources routine IT functions, in keeping with Agency policy. NCEA has, over the last several years, developed in-house expertise and acquired computer hardware and software to support geographic information system (GIS) services. The BOSC encourages NCEA to continue to expand such GIS capabilities in-house, as landscape and ecosystem level science (for both human health planning and ecological assessments) are developing rapidly in this area. NCEA should develop a proposal for additional funding in the GIS area for consideration by ORD's capital equipment committee. Development of guidance and tools for using GIS (including advanced spatial statistics) should be on NCEA's near-term priority list. Without a sizable core in-house expertise in this area, NCEA will be unable to remain on the cutting edge of the development of risk assessments for integrating traditional chemical stressors with emerging areas of endangered species management, invasive species, and land use planning. NCEA also will need other nontraditional specialists, such as ecologists, naturalists, and social scientists to meet these emerging challenges.

Recommendation 16: The BOSC strongly recommends that NCEA ask users to report something about themselves, so that they determine precisely who uses its Web site, recognizing that the Center may be under procedural and regulatory constraints in doing so. This information is critical, and there are various ways to obtain it. For example, NCEA can ask each user to provide name, occupation, location, and special interest (air, water, land, and so forth), and link this information to number of hits. It is critical for NCEA to understand its customers. Once the Center knows who they are, it can ask them what else they would like to see and in what form, thereby providing more effective outreach.

Communication Through Professional Organizations and Activities

NCEA staff members participate in scientific societies and conferences, and publish in peerreviewed journals. A table indicating the number of publications produced over time along with detailed appendices identifying the items, but not the specific journals, was provided in the NCEA Self-Study. Peer reviewed articles and those that had the greatest impact in the field were not identified. NCEA also provided biographical sketches of professional staff, which contained some references to professional organization activity as well publications, but not systematically. NCEA staff members are known to have held high-level positions within risk-related professional societies such as the Society for Risk Analysis (SRA), and the Society of Environmental Toxicology and Chemistry (SETAC).

NCEA staff members mention communicating with the public, including children in schools, but note that this has not been a priority. Communicating with these organizations is very different from communicating with peers, especially given the fact that there are no resources available. Obviously, communicating with non-peers is very desirable; however, this takes money and time. One wonders whether this function should be centralized in ORD or be contracted to a university or other organization.

<u>Recommendation 17</u>: NCEA should provide more systematic information about how its staff members target various channels to communicate their work and the impact of those communications.

<u>Recommendation 18</u>: NCEA should design its communication strategy around the audiences it wants to target, and explicitly identify those audiences recognizing that they may differ for different kinds of work.

2.2.3 Where does NCEA need to improve? What are the problems and challenges that NCEA faces in the next 5 years?

The NCEA staff identified three challenge areas: communication, partnerships, and integration. All of these are very important. With regard to communication, it seems unrealistic and infeasible for a largely science group to do any more than communicate with peers, unless EPA and ORD make a decision to do more than they have in the past to support other forms of communication. One should not underestimate the effort involved in developing a competent communications program. It requires lines, resources, and people who translate between NCEA scientists and the public. It will mean a new cultural group within NCEA. It would be an exciting challenge, but it most certainly would be a challenge. Most important, it would be foolish to even take on a challenge beyond Intranet/Internet, unless it is supported financially. As noted above, an alternative is to establish a working relationship with a university group. NCEA must absolutely avoid taking on a bigger role and diverting resources needed for science toward this end.

Finding collaborators is to be commended during a period of limited resources. As indicated in other sections of this report, NCEA previously has had public-private partnerships with the academic community on specific studies. The Center also has partnered with other ORD Laboratories and Centers in the preparation of MYPs. The collaborators NCEA seeks and obtains are varied and seem to be situation specific. How NCEA seeks out and identifies collaborators needs to be clarified.

The third challenge—that of integration—is to clarify NCEA's strategic niche as coordinator of the work of a number of different agencies, and communicate that role effectively to NCEA risk assessment partners. NCEA's partners include both the research organizations that provide effects and exposure data that NCEA uses in risk characterizations and the risk management organizations

that use NCEA-developed methods, models, tools, and data in conducting their own risk assessments.

2.2.4 What are the three to five most serious problems identified in the first BOSC review? How has NCEA responded to these problems and the BOSC recommendations related to them?

NCEA identified three problem areas: (1) understanding expectations of clients; (2) completing projects during realistic periods of time; and (3) the choice of breadth vs. depth in its work.

With regard to understanding of clients, NCEA has begun to step forward and meet with its EPA clients. Unfortunately, it has not undertaken a comprehensive client-based evaluation. The BOSC believes that such a survey should be conducted. Logically, it should be implemented by a neutral university or consulting firm to provide credibility.

With regard to completing its projects, NCEA mentions that much of its work involves complex, multi-step and multi-year projects. Nevertheless, it appears to have taken some positive steps on this front, by linking projects to Annual Performance Goals (APGs) and Annual Performance Measures (APMs).

Lastly, with regard to focusing its limited resources, NCEA noted that it has 10 percent of the ORD staff, and 8 percent of the ORD revenue (dollars). NCEA's explanation for relatively fewer resources given its staffing is that the Center has no "wet lab" facilities to maintain. This funding ratio is not currently a cause of concern to the BOSC. In light of limited resources, NCEA has made some notable choices, with which the BOSC agrees. It is portraying itself as the center of expertise for risk assessment. This means no longer trying to do every risk assessment, but instead focusing on the complex assessments and developing protocols for the standard ones. Second, more resources are devoted to ecological risk assessment. In addition, NCEA has dropped information management as a focus area. In other words, NCEA is focusing on the ecological and human aspects of risk, which the BOSC believes is a proper focus.

<u>Recommendation 19</u>: NCEA is encouraged to continue its discussions about future priorities. For example, in the area of risk assessment, the decision to specialize or be more broadly based is an important one. There are advantages and disadvantages to both approaches. This decision is fundamental to planning for staff recruitment in the ensuing years following the retirement of many of the current staff.

2.3 Performance

It is clear that NCEA is recognized nationally and internationally for its expertise in the areas of health and ecological risk assessments. The Center's Strategic Plan provides an excellent direction for its efforts in risk assessment. Indeed, NCEA's Strategic Plan represents a strong foundation for integration into EPA's overall mission and serves as a cornerstone for the major goals of ORD.

The staff and administrators of NCEA should be commended for their visionary goals and objectives for the Center and for their fulfillment of major responsibilities and obligations to the government and the public.

2.3.1 What other research organizations (U.S. or international) are similar in purpose and operation? How does NCEA's performance compare to the performance of these organizations (benchmarking)?

NCEA has had difficulty finding organizations against which to benchmark, because its operations and the combination of its programs are unique in the diversity of disciplines that are brought to bear and the nature of the work products. NCEA does not try to benchmark as a single organization, but elements of the operation can be benchmarked. Some international organizations undertake work analogous to NCEA, and could be useful for benchmarking. Several of the organizations NCEA has suggested include the WHO IPCS, the International Agency for Research on Cancer (IARC), and the Organization for Economic Cooperation and Development (OECD).

Within the United States, agencies that share similar functions in the area of publishing human health risk assessments are the Agency for Toxic Substances and Disease Registry (ATSDR), National Toxicology Program (NTP), Toxicology Excellence for Risk Assessment (TERA), Occupational Safety and Health Administration (OSHA)/National Institute for Occupational Safety and Health (NIOSH), and NIH.

<u>Recommendation 20</u>: NCEA should pursue identifying and evaluating organizations against which it can benchmark its work, and as NCEA has itself observed, this should not be at the level of the whole organization, but rather for key components. Benchmarking should reflect NCEA's work programs. For example, ecological risk assessment should be included in benchmarking.

2.3.2 Identify and discuss five cases where there has been a need for NCEA's research in EPA Program Offices or Regions. Include two to three examples of where this need has been met, and two to three examples where it has not. Why or why not?

During the October site visit by the BOSC Subcommittee, much was learned of NCEA's performance in relation to other organizations or offices within and outside of EPA. The several case studies presented in the NCEA Self-Study represent excellent examples of high-performance standards for NCEA and the significance and impact that the Center has within and outside of EPA. NCEA also provided some examples where there are still efforts needed by the Center to fulfill activities in the following two areas: (1) Cancer Risk Assessment Guidelines, and (2) Guidelines for Genomics and their Relationship to Risk Assessment.

<u>Recommendation 21</u>: The BOSC agrees with NCEA's assessment of the importance of the cancer risk assessment guidelines and guidelines for genomics and their relationship to risk assessment as areas of focus, and NCEA should integrate these guidelines into its overall strategy.

2.3.3 Identify and discuss five cases where there has been a need for NCEA's research by stakeholders outside of EPA (e.g., other federal agencies, state agencies, businesses, citizen groups, or other organizations).

The BOSC wishes to acknowledge the superb leadership and contributions of NCEA in five areas: hazard assessments under the Integrated Risk Information System (IRIS), risk assessment research and assistance to states on lead, watershed and causal assessments, global climate change assessment of the Great Lakes Region, and international risk assessment assistance.

Agencies such as ATSDR, Food and Drug Administration's (FDA) National Center for Toxicology Research (NCTR), and WHO's IPCS have benefitted from NCEA's expertise and experience in risk assessment. In fact, the BOSC recommends that NCEA communicate to ORD and EPA the many successes it has had with a variety of organizations. NCEA needs to take a more proactive approach in publicizing its accomplishments. The Center should utilize more fully the printed media and electronic technology to promote its accomplishments.

Recommendation 23: Because of the many services that NCEA provides to agencies and organizations within and outside of EPA, it is imperative that the Center's budget be a true reflection of its activities. More resources should be provided to NCEA to maintain the standards of excellence it has shown in the areas of health and ecological assessment. There must be flexibility in NCEA's budget to respond to short-term, long-term, and emergency demands, and such flexibility depends upon Agency-wide budgeting and planning processes.

Recommendation 24: For NCEA to perform at its highest standards of excellence, it is important for the Center, as well as other groups within EPA and all other federal agencies, to develop a strategy to replace the potential loss of many of its employees to retirement over the next 5-10 years. Decisions will have to be made on the types of disciplines to bring into NCEA, such as economics and the social sciences, which currently are not found in high numbers in the Center. Other emerging fields such as genomics, proteomics, and bioinformatics will have to be strengthened. The BOSC recommends that NCEA use a number of strategies to replace its workforce to the extent that they are consistent with its goals. These include:

- 1. Conduct recruiting visits to local universities to meet with students.
- 2. Encourage current/retired employees to visit their alma maters for recruitment purposes.
- 3. Develop closer ties to historically black colleges and universities.
- 4. Strengthen student internship programs.
- 5. Establish a database of the diversity of fellows recruited in to its Postdoctoral and AAAS Fellow Programs.
- 6. Draw upon recipients of STAR funds as potential recruits.
- 7. Offer to provide a seminar or tutorial at annual SRA and/or SETAC meetings.

<u>Recommendation 25</u>: NCEA products should be marketed extensively to key constituents, partners, other government agencies, and the public. These products may include such items as the Benchmark Dose software and the Exposure Factors Handbook. Every effort should be made to bring in other groups, not normally associated with NCEA, such as NIH and National Science Foundation (NSF), so that its products become better known.

<u>Recommendation 26</u>: It is critical for NCEA to have a definite plan in place to maintain strong lines of communication among the various groups with which it interacts. The area of performance becomes an issue if NCEA does not adequately and effectively

communicate between its staff and management leaders, between its multi-located sites (Washington, DC; Cincinnati, OH; and RTP, NC), between NCEA and ORD, and between NCEA and other organizations inside and outside EPA in a manner consistent with its needs.

2.4 Measures of Success and Future Needs

2.4.1 How does NCEA measure the efficacy and results of its organization's performance? Target indicators? Metrics of success? Show quantitative measures of performance.

The ORD Strategic Plan lists measures of success for each of its goals. NCEA's measures, to a large extent, can be framed or aligned with the ORD measures of success, as well as tailored to NCEA's specific needs.

In its self-study, NCEA addressed this by underscoring its use of primarily qualitative measures of success, recognizing that the organization has few direct measures of organizational performance outside of gross Web usage statistics or number of scientific papers published.

Examples cited of the use of qualitative measures include feedback obtained through retreats and reactions of clients and the public. NCEA is interested in how it can ascertain performance with respect to client and user needs; however, an identification of the users or clients is a critical first step. This includes looking to the future to determine potential clientele. At the present time, little systematic tracking or documentation of clientele has been undertaken.

NCEA identifies two kinds of measures—one related to its products and the other related to organizational performance. Products are primarily evaluated through peer review mechanisms, and NCEA may want to think about what quantitative measures would be useful here; for example:

- ♦ Distribution of the products across peer review outcomes.
- ♦ Whether certain research areas are less successful than others in terms of peer review.
- ❖ Frequency of staff service on peer review committees.

In other words, some useful diagnostics can be applied.

NCEA indicated that its evaluations of employee satisfaction and morale are primarily accomplished through the organizational climate survey. Questions used in this survey were subsequently given to the Subcommittee. It is commendable that such an evaluation mechanism is ORD-wide so that NCEA can determine how it performs relative to other ORD entities. It is important to have surveys repeated over time to ascertain the extent of improvement and to identify where improvements are needed.

NCEA relates to at least two different client groups. The first group is internal to EPA, consisting of Program and Regional Offices. The second is the public. The first BOSC review recommended more evaluations of these groups. NCEA staff believes that the measure of satisfaction of the Program and Regional Offices and the Agency in general is reflected in the continuation of resources for its programs. A measure of satisfaction for the public is reflected in part by who attends NCEA-sponsored events. The BOSC believes that a more formal process to identify stakeholders and clients is needed.

<u>Recommendation 27</u>: NCEA should expand its measures of success, for example, through well-designed surveys targeted to existing and potential users, expanding the use of quantitative measures where possible. Identifying target clients is critical to this undertaking.

2.4.2 How does NCEA use research results to set new research priorities, plan research, and discharge its mission?

Examples

In the NCEA Self-Study, the Center identified two cases in which previous projects were used to set new priorities and plan research. These were the development of the Ecological Risk Assessment Guidelines in 1998, and Aquatic Stressor Identification Research.

In addition, the biographical sketches contain a number of examples of where the mission to develop the state-of-the-science of risk assessment has been accomplished in the context of research projects. This is particularly true in the area of modeling. Some examples are in the areas of: reference concentrations (RfCs), pharmacokinetic modeling from the dioxin risk assessment, and the IEUBK (Integrated Exposure Uptake Biokinetic) Model.

NCEA has been a leader in developing the risk assessment guidelines. Many professional societies have taught risk assessment guidelines courses using NCEA's work.

Success in Communication

NCEA's success is, at least in part, a function of the degree to which its work is communicated and known to others. The Center staff believes its work is known among the agencies with which it works. NCEA is viewed as a potential leader in global climate change. The Center does some of the cutting-edge research and assessment in this area, and transfers it to other agencies, including the U.S. Department of Transportation's new climate program, and the NIH for joint health assessments. NCEA should continue to share what its has learned with other agencies.

It is more difficult to ascertain how well the general public knows of and understands NCEA's work. NCEA indicated that contributing to its lack of visibility with the general public is the fact that NCEA products are in the public domain and are no longer identified with NCEA once someone commercializes them. There is little that can be done about this, except building in some control at the beginning. For example, in the development of "Risk Assistant," NCEA worked with a company through a Cooperative Research and Development Agreement (CRADA) that granted the government control over the product.

Products are better known outside the Agency than inside the Agency, and outside the United States than inside the United States. An example cited was the Stressor Identification document. Three consulting companies were already advertising that they knew how to use the document prior to its release.

The issue of the value of having NCEA's work better known was discussed at the site visit. NCEA staff thought it was good for morale, but did not think it would necessarily generate more staff or financial resources. They also thought that being better known would help in recruiting.

<u>Recommendation 28</u>: NCEA has to develop processes whereby its best work is brought to the attention of internal and external audiences, through venues such as workshops at professional association meetings, refereed articles, etc. It should also carefully track and evaluate this outreach effort. NCEA should examine the benefits of a more frequent use of CRADAs to market its products under its own name.

2.4.3 Are the human resources at NCEA's disposal appropriate for its mission, goals, and objectives?

NCEA recognizes that staff is limited, and many causes for this difficulty and options to overcome it were discussed. NCEA identified the low turnover of staff, in part because ORD has the oldest workforce across the Agency, as being both a strength and a liability as it limits the ability to bring in new talent. In the NCEA Self-Study, the Center indicates that it uses various personnel authorities to bring in new talent (NCEA Self-Study Chapter 4, p. 4), such as the post-doctoral, internship, visiting scholar, fellows, and Intergovernmental Personnel Act (IPA) programs.

The areas where there are deficiencies are indicated in Chapter 4 (p. 3) of the NCEA Self-Study. Genomics, proteomics, bioinformatics, and nanotechnology are all areas of investment. The MYPs underscore the fact that NCEA should not just replace someone with the same discipline but look forward to what areas of research are desirable and what skills would meet those needs. The fact that 25 percent of NCEA's staff is eligible to retire in the next 5 years might provide the Center with flexibility to expand into those needed areas if, in fact, these retirements occur. NCEA looks for the best and brightest, rather than skill-based staff. If no skills are available in-house, NCEA will go to other parts of EPA or to outside agencies.

NCEA has considered training as a means of expanding the expertise of its existing staff, but it is difficult to move people to training locations; thus, long distance learning becomes attractive. NCEA is conducting a pilot training program focused on ecological risk assessment training.

Productivity measures are needed for the workforce, and benchmarking would help establish a reference point for such measures. Presently, NCEA implicitly and explicitly uses ORD to benchmark its performance; for example, one measure in the NCEA Self-Study (Chapter 4, p. 5) states "NCEA has approximately 8 percent of the ORD budget yet produces over two-thirds of Category 1 and 2 products." Numerous ways of improving productivity are listed, which are difficult to assess in terms of their actual impact on productivity. It is important to know how NCEA plans to advance in these areas and whether it has sufficient resources to do so.

<u>Recommendation 29</u>: NCEA should think through its hiring plan and make it conform with its strategic plan, at least 5 years out.

2.4.4 Does NCEA have the appropriate mix of workforce, facilities, and infrastructure to plan, prioritize, implement, and communicate its results?

To address this issue, the BOSC Subcommittee requested from NCEA a breakdown of its work and workforce by goals and by discipline, and if possible, to link disciplines to goals to reflect the match of individuals to work. These were the findings:

By <u>location</u>, NCEA's total workforce in FY 2001 was about 181, and it was distributed as follows: 29 percent in the Immediate Office in Washington, DC; 38 percent in the Washington, DC Division; 14 percent in the RTP Division; and 19 percent in the Cincinnati Division.

By type of staff (administrative/scientific), scientific staff accounts for about two-thirds of the staff and the remaining third is administrative staff. Although proportion of staff devoted to administration may seem to be large, NCEA has determined that overall productivity is enhanced by reducing the red tape and paperwork burdens on the staff scientists by providing dedicated support staff. There are eight categories of support staff defined, including quality assurance, human resources, financial management, budget development, operations, and secretarial support. The division between the administrative and scientific categories is functionally defined.

By <u>discipline</u>, environmental science and environmental health science, toxicology, and ecology are the highest ranking (in order) for the scientific disciplines. Other disciplines account for fewer than 10 positions each. Social science is not listed. NCEA is moving more heavily into the area of ecology, though health still dominates, accounting for 85 percent of the budget.

By type of project (extramural/intramural), although funds are evenly split between extramural and intramural projects, the staff are not distributed evenly. The management of extramural research places a big demand of time and effort on technical staff, so a centralized administrative staff has been given that responsibility. Some mechanisms exist to function as an umbrella for the management of other funds. For example, AWWRF research is a congressional earmark—there are 60 project in total and six are ongoing concurrently. A board, with representation from across ORD and three offices in the Office of Water, helps to select the projects. Because it is pass through funding, those tend to be handled differently.

By <u>GPRA goal</u>, 44.6 percent of the staff is devoted to Sound Science (Goal 8), and about 15 percent each is devoted to Clean Air (Goal 1) and Clean/Safe Water (Goal 2); the rest of the GPRA goals are represented by approximately 10 percent or less of the staff.

Recommendation 30: Each new position that becomes available is a precious resource in a government agency. Therefore, it is essential that NCEA openly and frequently review its hiring needs against its goals and objectives as articulated in the Strategic Plan and the MYPs.

3.0 RECOMMENDATIONS

- 1. NCEA should await the next ORD Strategic Plan revision before updating its own strategic plan to bring the goals of the two plans into greater alignment.
- 2. NCEA should continue to identify the research needed to reduce uncertainties in risk assessment and to provide these research needs as input to ORD's annual budgeting process.
- 3. NCEA's response to unanticipated events is notable and critical, and in some way these needs should be integrated into the NCEA, ORD, and EPA strategic planning processes, recognizing that these particular needs are episodic, unexpected, with often uncertain and unpredictable resource needs. NCEA should assess whether, in fact, the mechanisms do exist for effective emergency response and should ensure that emergency provisions are a part of its plan.
- 4. The BOSC endorses NCEA's move away from conducting a large number of routine risk assessments and urges NCEA to continue to focus on precedent-setting or national-scale assessments. The process by which NCEA decides on which risk assessments to undertake should be articulated.
- 5. With respect to its work in general, the BOSC suggests that NCEA look across the Integrated Research Strategies or Multi-Year Plans, and identify areas of interest and focus over the next 5 to 10 years.
- 6. The BOSC recommends that NCEA combine risk management and risk assessment in its work, that is, coordinate analytic and deliberative processes as recommended in the National Research Council's report *Understanding Risk* (1996). Also, NCEA should proactively incorporate life cycle assessment. Additional resources may be needed to undertake this task.
- 7. The BOSC encourages NCEA to be more proactive in identifying potential clients for its work products as a basis for focusing and targeting its programs.
- 8. NCEA should continue to enhance communication among Division Directors to foster interdisciplinary work across the divisions. It should consider methods for integrating staff, including details and rotations among divisions, occasional interdisciplinary science retreats on topics requiring input from across divisions, and other performance incentives to establish collaborative projects.
- 9. For NCEA to coordinate risk assessment functions among its various divisions, its current functions in this area should be clearly articulated.
- 10. NCEA should explore measures of the extent, diversity, and nature of its intra-ORD and intra-EPA activities and keep track of them on a regular basis, perhaps incorporating them into the GPRA framework. These measures should include the nature of those interactions and their outcomes. This should occur on a regular basis to ensure that intra-EPA integration of research is occurring and how it is occurring.
- 11. To better accomplish those goals requiring social science expertise, as well as to further the development of guidance in risk communication, NCEA is encouraged to consider hiring social

- scientists, either as AAAS Fellows, post-docs, or permanent staff drawn from the fellow and post-doctoral group.
- 12. The BOSC endorses NCEA's practice of establishing interdisciplinary teams, with human health risk assessors and ecological risk assessors working together on the same assessments (Global Climate Change and "place-based" assessments rather than single chemical assessments, are examples).
- 13. The BOSC encourages NCEA to continue to increase its interest and investment in ecological risk assessment. While other portions of the government also conduct research in human health risk assessment and toxicology, the EPA is the principal agency conducting ecological assessments and developing guidance for such work.
- 14. NCEA has made progress in integrating ecology and human health assessments, and it is encouraged to continue to be more aggressive in these initiatives as there is a need in the risk assessment community to move forward more quickly on integration.
- 15. To evaluate and communicate how NCEA accomplishes its risk assessments, NCEA needs to describe its process of synthesis and integration across the stages of risk assessment and how it engages the different entities within ORD, EPA, and the research community in producing such integration.
- 16. The BOSC strongly recommends that NCEA ask users of the NCEA Internet site to report something about themselves, so that the Center can determine precisely who uses the site, recognizing that NCEA may be under procedural and regulatory constraints in doing so. This information is critical, and there are various ways to obtain it. For example, NCEA can ask each user to provide name, occupation, location, and special interest (air, water, land, and so forth) and link this information to number of hits. This is critical for NCEA to understand its customers. Once the Center knows who they are, it can ask them what else they would like to see produced and in what form to providing more effective outreach.
- 17. NCEA should provide more systematic information about how its staff members target various channels to communicate their work and the impact of those communications.
- 18. NCEA should design its communication strategy around audiences it targets, and explicitly identify those audiences recognizing that they may differ for different kinds of work.
- 19. NCEA is encouraged to continue its discussions about future priorities. For example, in the area of risk assessment, the decision to specialize or be more broadly based is an important one. There are advantages and disadvantages to both approaches. This decision is fundamental to planning for staff recruitment in the ensuing years following the retirement of many of the current staff.
- 20. NCEA should pursue identifying and evaluating organizations against which it can benchmark its work, and as NCEA has itself observed, this should not be at the level of the whole organization, but rather for key components. Benchmarking should reflect all of NCEA's work programs. For example, ecological risk assessment should be included in benchmarking.

- 21. The BOSC agrees with NCEA's assessment of the importance of the cancer risk assessment guidelines and guidelines for genomics and their relationship to risk assessment as areas of focus, and NCEA should integrate these guidelines into its overall strategy.
- 22. NCEA needs to use a more proactive approach in publicizing its accomplishments. It should utilize more fully printed media and electronic technology to promote its accomplishments.
- 23. NCEA's budget needs to be a true reflection of its activities. More resources should be provided to NCEA to maintain the standards of excellence it has shown in the areas of health and ecological assessment. There must be flexibility in NCEA's budget to respond to short-term, long-term, and emergency demands, and such flexibility depends upon Agency-wide budgeting and planning processes.
- 24. For NCEA to perform at its highest standards of excellence, it is important for the Center, as well as other groups within EPA and all other federal agencies, to develop a strategy to replace the potential loss of many of its employees to retirement over the next 5 to 10 years. Many options are available to do so, but must be evaluated with respect to their consistency with NCEA needs.
- 25. NCEA products should be marketed extensively to key constituents, partners, other government agencies, and the public.
- 26. It is critical for NCEA to have a definite plan in place to maintain strong lines of communication among the various groups with which it interacts.
- 27. NCEA should expand its measures of success, for example, through well-designed surveys, targeted to existing and potential users expanding the use of quantitative measures where possible. Identifying target clients is critical to this undertaking.
- 28. NCEA has to develop processes whereby its best work is brought to the attention of internal and external audiences, through venues such as workshops at professional association meetings, refereed articles, etc. It should also carefully track and evaluate this outreach effort. NCEA should examine benefits of more frequent use of CRADAs to market its products under its own name.
- 29. NCEA should think through its hiring plan and make it conform with the Center's strategic plan, at least 5 years out.
- 30. Each new position that becomes available is a precious resource in a government agency. Therefore, it is essential that NCEA openly and frequently reviews its hiring needs against its goals and objectives as articulated in the Strategic Plan and the Multi-Year Plans.

APPENDIX A: List of Documents Made Available to the Subcommittee

NCEA, "Topics for Discussion," October 10 and 11, 2001 (PowerPoint Presentation).

Information Requests from Members to NCEA:

NCEA's Ongoing or Recently Completed Research Activities, Organized Alphabetically by Project Title and by GPRA Goal.

Biographical Sketches of NCEA Professional Staff.

U.S. EPA, ORD, FY 2001 Mid-Year Performance Review for the NCEA, ORD, U.S. EPA. July 3, 2001.

Government Performance and Results Act (GPRA) Goals, Objectives, Subobjectives, APGs, and APMs for NCEA: FY 99-FY 01. March 1, 2001.

NCEA Self-Study 2001.

- U.S. EPA, ORD, BOSC, Program Review of the National Center for Environmental Assessment (NCEA). Final Report. Washington, DC: U.S. EPA, ORD, BOSC. April 1998.
- U.S. EPA, ORD, NCEA, "Progress on BOSC Subcommittee's Recommendations to NCEA." Washington, DC: U.S. EPA, ORD, NCEA. January 6, 1999.
- U.S. EPA, ORD, NCEA, Strategic Plan for the National Center for Environmental Assessment. Washington, D.C. January 31, 2000 (Review Draft).
- U.S. EPA, ORD, BOSC, Management Review of the Particulate Matter Research Program. Washington, DC: U.S. EPA, ORD. December 2000.
- U.S. EPA, Office of Research and Development (ORD), Office of Research and Development Strategic Plan. Washington, DC: U.S. EPA, ORD, EPA/600/R-01/003. January 2001.
- U.S. EPA, ORD, NCEA, Strategic Plan for the NCEA. ORD Review Draft. January 31, 2000.

Various program documents.

APPENDIX B: Summary of NCEA Actions With Respect to the Recommendations of the 1998 BOSC Review

NCEA submitted formal responses to the recommendations of the 1998 BOSC review to the Assistant Administrator for Research and Development on January 6, 1999. This section summarizes how the many NCEA actions described in this report update those responses. In some cases, the sections above address these recommendations fully, and the appropriate sections are referenced where that is the case. Where the particular recommendations from the previous review have not been revisited, they are indicated as such.

1998 Recommendations and Summary of NCEA Responses

- 1. Continue to identify and communicate the following to Program Offices and ORD: (1) changes that are occurring within NCEA; (2) the performance and value of NCEA; and (3) the positive actions and directions being taken by NCEA to align with and implement the ORD Strategic Plan. Section 2.2.2 identifies mechanisms for communication. In 1999, NCEA identified the risk assessors meeting and other means of communication.
- 2. Develop a strategic plan that outlines an approach that brings focus and balance to support its core research capabilities to address ORD Strategic Plan elements, including an explicit plan for addressing the imbalance between human health and ecology by strengthening the infrastructure for ecological research. See Sections 2.1.1 and 2.1.7. The NCEA plan was completed on January 31, 2000.
- 3. Consult the advice and suggestions from previous Agency Science Advisory Boards, NRC reports, and separate reviews of ORD (e.g., Reducing Risk, Safeguarding the Future, Beyond the Horizon). In 1999, NCEA indicated that the Agency is re-reviewing these documents and incorporating elements into the NCEA Strategic Plan.
- 4. Develop additional efforts and mechanisms to improve communication of the NCEA strategic thinking and initiatives to the staff. See Section 2.2.2. In 1999, NCEA identified "skip-level" meetings with staff to strengthen communication, and increased its use of the Intranet as an effective internal communication tool.
- 5. Develop strategic initiatives that are cross-cutting through Agency and ORD priority issue areas. See Sections 2.1.1 and 2.1.2. Priority issue areas are identified in the NCEA Strategic Plan.
- 6. Place a greater emphasis on understanding the expectations of its clients, including those at the Assistant Administrator level, and then work to ensure that NCEA initiatives are in place to fulfill those needs. To ensure that NCEA is successfully satisfying its various clients, a comprehensive client-based evaluation of both NCEA program support and its Director's leadership should be initiated. See Section 2.2.4, Item #1; the BOSC recommends further strengthening client identification and evaluation.
- 7. Develop and cultivate improved relationships with key Laboratory-based partners within ORD and the Agency. See Section 2.2.3.
- 8. Develop personnel incentives and recognition programs that align with its strategic priorities. Several of these initiatives were identified by NCEA in 1999.

- 9. Set a goal to reach closure for all projects NCEA initiates within preplanned time projections. See Section 2.2.4, Item #2. In 1999, NCEA indicated its use of milestone reporting as well as GPRA to assist in moving projects toward closure.
- 10. Develop an improved process to track cost and effort investments for project conduct so that management can better visualize which activities are consuming resources. In 1999, NCEA indicated this was a goal for the future, and looked toward the recent hiring of a new Deputy for Management as a step in achieving it.
- 11. Identify criteria, after appropriate client consultations, that would represent stakeholder-supported benchmarks for improving NCEA productivity, quality, and client service objectives. NCEA should then apply these criteria to a focused benchmarking exercise. See Section 2.3.1.
- 12. Implement specific strategic plans and efforts to acquire ("mine") and integrate priority information to the benefit of NCEA, ORD, and EPA. In 1999, NCEA indicated that it had developed a 5-year "information management" (IM) plan to use its information for its benefit and the benefit of ORD and EPA.
- 13. Use the best expertise and scientific organizations that can be found for scientific collaboration, without undue reliance on location. See Section 2.1.4.
- 14. Identify opportunities for interactions with national academic Centers of Excellence that are funded by ORD; develop processes to strengthen interactions with academic researchers through mechanisms such as competitive grants, contracts, and CRADAs; and create an external advisory group to help NCEA identify external opportunities to interact with the "nation's best research institutions." See Section 2.1.5.
- 15. Develop a clear plan to improve the balance between ecological and human health risk assessment, including resources staff, and expertise. See Section 2.1.7.
- 16. Establish an outside advisory group to help develop a strategic plan for approaching ecological risk assessments. In 1999, NCEA indicated it would keep this in mind, and use the peer review process in the short term.
- 17. Develop and implement a long-term leadership development plan/process for the Director and Associate and Assistant Center Directors. In 1999, NCEA indicated it would consider doing this.
- 18. *Implement a mentoring and skills enhancement program for NCEA staff.* See Sections 2.4.3 and 2.4.4. In 1999, NCEA indicated this was primarily done for AAAS Fellows and post-doctorate hires, and the Center would attempt to strengthen it for other staff in the future.

APPENDIX C: NCEA Self-Study